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2

㉔ 特許請求の範囲

1 支持板の上部に 1~10 $\mu$ ℓ の内容積を有する薬液容器及び該薬液容器内の規定量の薬液を押し出す押圧体と、支持板の下部に、該支持板に対して 45°~90° の角度を有しかつ上記の薬液容器内と連通するように取付けられた 10~100 $\mu$  径の注射針とを備えてなるミクロ注射器。

2 薬液容器が筒状であつて、薬液容器内の規定量の薬液を押し出す押圧体が、薬液容器に摺動可能に嵌挿されたピストンと、該ピストンにピストンロッドを介して取付けられた押圧板とからなる特許請求の範囲第 1 項に記載のミクロ注射器。

3 支持板の上部に設けられた薬液容器が弾性材料からなる特許請求の範囲第 1 項記載のミクロ注射器。

4 弾性材料からなる薬液容器が断面半球状に形成されてなる特許請求の範囲第 3 項に記載のミクロ注射器。

5 弾性材料からなる薬液容器内の規定量の薬液を押し出す押圧体が、該薬液容器を包囲して支持板の上部に取り付けられたドーム状の弾性体の中に存在する気体を有するドーム状の弾性体からなる特許請求の範囲第 3 項に記載のミクロ注射器。

6 弾性材料からなる薬液容器内の規定量の薬液を押し出す押圧体が、該薬液容器と僅かな間隔を保って包囲するように支持板の上部に取り付けられたドーム状をした中実状の弾性体からなる特許請求の範囲第 3 項に記載のミクロ注射器。

7 支持板の上部に 1~10 $\mu$ ℓ の内容積を有する薬液容器及び該薬液容器内の規定量の薬液を押し出す押圧体と、支持板の下部に、該支持板に対して 45°~90° の角度を有しかつ上記の薬液容器内と連通するように取付けられた 10~100 $\mu$  の注射針と、この注射針を若干のスペースを保って包囲するスポンジ、ゴムその他これに類する弾性材料の皮張体とを備えてなるミクロ注射器。

8 上記の皮張体が、金属材料、硬質紙、硬質合成樹脂材料によりスリーブ状に形成されてなる特許請求の範囲第 8 項に記載のミクロ注射器。

9 上記のスリーブ状皮張体が、支持板に対して相対的に摺動可能に取付けられている特許請求の範囲第 8 項に記載のミクロ注射器。

10 10 支持板の上部に設けられる薬液容器が弾性材料からなる特許請求の範囲第 7 項に記載のミクロ注射器。

11 弾性材料からなる薬液容器が断面半球状に形成されてなる特許請求の範囲第 10 項に記載のミクロ注射器。

12 弾性材料からなる薬液容器と、該薬液容器内に収容された規定量の薬液を押し出す押圧体が、薬液容器を包囲して支持板の上部に取り付けられたドーム状の弾性体の中に存在する気体を有するドーム状の弾性体である特許請求の範囲第 10 項に記載のミクロ注射器。

13 弾性材料からなる薬液容器内の規定量の薬液を押し出す押圧体が、該薬液容器と僅かな間隔

を保つて包囲するように支持板の上部に取付けられたドーム状の中実状の弾性体から成る特許請求の範囲第10項に記載のマイクロ注射器。

#### 発明の詳細な説明

##### 〔産業上の利用分野〕

本発明は、例えばカルシトニン、プロスタグランジン等の生理活性物質の薬液を微量注射するために好適なマイクロ注射器に関する。

##### 〔従来の技術〕

例えばカルシトニン、プロスタグランジン等の生理活性物質の薬液を人体へ注入する場合、その必要な注入量は極めて微量（ $1 \sim 10 \mu\ell$ ）である。この種の薬液注入は、例えば先端に注射針を備えたシリンダに挿抜可能に嵌挿されたピストン形式の注射器により行っていた。しかしながら、このような注射器の場合、注射器自体やその注射針の針径（ $500 \sim 2500 \mu$ ）が大きいために  $1 \sim 10 \mu\ell$  の微量注入は不可能であり、その注入量を約  $1 \text{ ml}$  程度に希釈増量せしめなければならず、かつ注入時には針径が大きいために皮下等に痛みを与える欠点があった。又、注射針を皮下等に刺し込む際は、注射器を持たない片方の手の指先で、患者の注射すべき部位の皮膚面をいちいち突張って拡張せしめ、注射針の刺部が入り込み易い状態にしなければならないので、面倒であった。

更に、注射針の刺部を人体内に刺し込むに際しても、医師等の経験側で適当深さに刺し込むため、望ましい注入部位より  $0.5 \sim 3 \text{ cm}$  も深く刺し込んでいるのが実情である。

##### 〔発明が解決しようとする問題点〕

このように、皮下、皮内や筋肉注射により多少異なるが、一般的に注入部位より  $0.5 \sim 3 \text{ cm}$  も深く刺し込んでいるため、血管系統、神経系統、皮下組織等を傷つけたり、更には、大腿四頭筋拘束症等の筋注薬害を起因させてしまうおそれがあり、極めて危険性を伴うものであった。

本発明者らは、上記のような従来の種々の問題点を解決すべく苦心の研究を行った結果、カルシトニン、プロスタグランジン等の生理活性物質のように微量注射を目的とする注射器を開発することに成功した。

本発明の目的は、微量（ $1 \sim 10 \mu\ell$ ）の生理活性物質の薬液を、皮下又は皮内に殆ど無痛の状態で注入でき、しかも皮下組織を傷つけたりあるい

は破壊とかの薬害等のおそれを確実に防止し得るようにしたマイクロ注射器を提供するにある。

##### 〔問題点を解決するための手段〕

上記のような種々の問題点を解決する本発明の

5 手段は、支持板の上部に  $1 \sim 100 \mu\ell$  の内容積を有する薬液容器及び該薬液容器内の規定量の薬液を押し出す押圧体と、支持板の下部に、該支持板に対して  $45^\circ \sim 90^\circ$  の角度を有しかつ上記の薬液容器内と連通するように取付けられた  $10 \sim 100 \mu$  径の注射針とを備えてなるマイクロ注射器を提供するにある。更にまた、本発明は、支持板の上部に  $1 \sim 10 \mu\ell$  の内容積を有する薬液容器及び該薬液容器内の規定量の薬液を押し出す押圧体と、支持板の下部に、該支持板に対して  $45^\circ \sim 90^\circ$  の角度を有しかつ上記の薬液容器内と連通するように取付けられた  $10 \sim 100 \mu$  の注射針と、この注射針を若干のスペースを保つて包囲するスポンジ、ゴムその他これに類する弾性材料の皮張体とを備えてなるマイクロ注射器を提供するにある。

##### 〔作用〕

注射すべき皮膚面の近辺に支持板の一端縁を押し当て、また支持板の他端側縁を皮膚面方向に近ずける。すると注射すべき皮膚面が皮張される。この、皮張下において支持板をさらに皮膚面方向に近ずけて、該支持板に設けた極細注射針の刺部を皮下または皮内に刺し込めばよい。したがって、本発明の注射器によれば、注射すべき皮膚面をいちいち指先で突張って注射針の刺部が入り込み易くする等の面倒な操作をいっさい必要としないものである。

以下本発明の数個の実施例について詳しく説明するが、これによつて限定されるものではない。

##### 第1実施例の構成

第1図ないし第3図に示した本発明による注射器1は支持板2を備えている。支持板2は、例えば金属材料、合成樹脂材料その他これに類する材料により円形状に形成されている。支持板2は、例えば直径  $1 \sim 2 \text{ cm}$ 、厚さ  $2 \sim 5 \text{ mm}$  の取り扱い易い大きさに選定してある。支持板2は、本例のように必ずしも円形状に形成する必要はなく、例えば角形状、楕円形状その他任意の形状に形成することができる。支持板2の中央部には、直径  $0.05 \sim 0.1 \text{ mm}$  の流通孔3が形成してある。支持板2の下面には、取付凹部4が形成してある。注射針5

の刺部 6 と反対側の端部 7 は流通孔 3 に直接挿入して固定してある。勿論、この取付けは、挿入のみに限定されず他の適当な手段により行うことができる。注射針 5 は、ステンレス等の金属材料や合成樹脂材料により直径 10~100 $\mu$ 、長さ 1~5 mm のマイクロ針に形成してある。なお、注射針 5 を支持板 2 に取付けるに際して重要なことは、注射針 5 が該支持板 2 の下面に対して 45°以上、とくに、好適には 60°~90°の角度を保って取付けられていることである。注射針 5 がこのような角度を有し、かつ 10~50 $\mu$  という極細の構造に形成されていることにより、注射針 5 の刺部 6 が、皮膚面に殆んど痛みを感じさせることなく皮膚面に鋭く切裂きそのまま皮下または皮内にスムーズに入り込んでゆくことになる。

上記支持板 2 の上面には、流通孔 3 を包囲して薬液容器 8 が設けてある。薬液容器 8 は、1~10 $\mu$  の薬液が収容される大きさに形成され、従って、この薬液容器 8 にカルシトニン、プロスタグランジン等の生理活性物質の溶液が一定量収容される。薬液容器 8 には、ピストンロッド 9 が挿入され、該ピストンロッド 9 の先端には、シリコンゴム等の弾性材料からなるピストン 10 が取付けである。ピストン 10 は、薬液容器 8 の開口縁部に形成したストツパ片 11 によつて薬液容器 8 から離脱しないようにしてある。ピストンロッド 9 は、金属材料、合成樹脂材料からなる押圧体 12 と一体に形成してある。なお、図中において、符号 13 はカバー兼ストツパである。このストツパ 13 は、その一部分を軸方向に切り欠いて開口部が形成してある。この開口部は、薬液容器 8 の外径よりも若干大きくなっている。したがって、この開口部より薬液容器 8 が支障なく挿抜され、カバー兼ストツパ 13 が支持板 2 と押圧体 12 との間に着脱可能に配装される。

次に、注射器の使用について説明する。先ず、カバー兼ストツパ 13 を支持板 2 と押圧体 12 との間からはずし、押圧体 12 を第 1 図において下方へ押し込む。そして、注射針 5 の刺部 6 を生理活性物質容器を有するバイアル壺等に挿入し、押圧体 12 を前記とは反対の方向に引き上げる。すると、ピストン 10 により薬液が注射針 5 を介して薬液容器 8 内に一定量だけ充填される。

そこで、実際に人体に対して皮下又は皮内に注

入するには、支持板 2 の一端縁部すなわち、注射針 5 の刺部 6 が指向されている縁部 2 a 側を皮膚面 14 の注射すべき部分の近くに押し当てる（第 2 図参照）。この押し当てた位置を支点にして支持板 2 の他端縁部 2 b 側を皮膚面 14 に近づける（第 3 図参照）。すると、支持板 2 の一端縁部 2 a により、皮膚面 14 が、一端縁 2 a よりも、さらに外方向へ突張られる状態となる。

したがって、皮膚面 14 の注射すべき部分が皮張されると共に適度の傾斜角度を保った注射針 5 の刺部 6 が皮膚面 14 を傷つけそのまま皮下または皮内にスムーズにさし込まれる。これと同時に押圧体 12 をスムーズに押圧してピストン 10 を薬液容器 8 内に押し込むことにより、薬液容器 8 内の薬液を流通孔 3 から流出させ、注射針 5 を介して皮下又は皮内に注入すればよい。注射針 5 は支持板 2 に対して適度の傾斜角度を保って取付けられているため、支持板 2 の一端縁 2 a を中心にして他端縁 2 b 側を皮膚面 14 方向に近づけると、その刺部 6 が皮膚面 14 に斜め方向から刺し込まれる。

したがって、注射針 5 は多くても表皮 3 mm（実際には 1~2 mm）以下となり、皮内に必要以上に深く入り込むおそれはなく、極めて安全に使用できる。又、上記の場合、支持板 2 により注入すべき皮膚面を皮張させながら傾斜配置の極細の注射針 5 を斜め方向から皮下に刺し込む状態は、ちょうど「蚊」が吸血を行うときに、先ず脚で皮膚面を押えつけて皮張させた後、極細の鋭い刺針片を皮下に突き刺す状態と同じような感じであつて、痛みは殆ど皆無に近いものである。

次に、第 4 図に示した実施例の注射器は第 1 図の実施例による注射器と殆ど同じであるが、ただ、この実施例の場合には、流通孔 3 と薬液容器 8 の内径とが同径になっている。したがって、この薬液容器 8 に挿入されるピストン 10 の形状が第 1 図の実施例と異なる。勿論、薬液容器 8 は 1~10 $\mu$  l の薬液を充填し得る大きさに選定されている。又、この実施例における注射器の作用については、第 1 図の注射器の場合と同じであるため、説明は省略する。第 5 図に示した実施例の注射器は、第 1 図の実施例による注射器と殆ど同じであるが、ただ、この実施例の場合には、注射針 5 を支持板 2 の中央部でなく、支持板 2 の一端縁

7

部 2 a 側に位置して 80°~90°の傾斜角度を保つて取付けてある。

第 6 図に示した実施例の注射器は、支持板 2 の噛めんに注射針 5 を包囲下状態でスポンジ、ゴム、可撓性合成樹脂その他、これに類する材料からなる皮張体 15 を設けた構造、第 1 図に示した実施例のちゅうしやきと異なる。皮張体 15 は、末広がり状、いわゆる断面形状がラツパ状に形成されることが望ましい。しかるに、注入に際して皮張体 15 を皮膚面 14 に当節させ押圧体 12 を押圧することにより、皮張体 15 の弾力性によって、注入すべき部分の皮膚面が皮張され、注射針 5 の刺部 6 が第 1 図の実施例の場合と同様に皮下にスムーズに刺し込まれることになる。上記の皮張体 15 は、その弾力性をより向上化させるために皮張体の円周方向の適当な間隔を保つてスリットを入れた構造にしてもよい。

第 7 図に示した実施例の注射器は、注射針 5 と薬液容器 8 とを一体とし、かつ皮張体 15 を設けた構造が第 1 図に示した実施例の注射器と異なる。すなわち、皮張体 15 は、金属材料、硬質合成樹脂材料その他、これに類する材料により形成してある。皮張体 15 は、中空円筒状に形成されており、その上端縁が支持板 2 の上面と同一平面となるように取付けてある。皮張体 15 には、上端に薬液容器 8 を一体に有する注射針 5 が若干のスペースを保つて嵌挿してある。薬液容器 8 は、断面があらまし皿状に形成され、該薬液容器 8 内には、第 1 図に示した実施例と同じ構造のピストン 10、ピストンロッド 9 が嵌挿してある。ピストンロッド 9 は押圧体 12 と一体になっている。本例の注射針は、支持板 2 3 の下面に対してほぼ 90°の角度をなす。支持板 2 と押圧体 12 との間には、カバー兼ストツパ 13 が第 1 図の実施例と同様に着脱可能に配装され、このカバー兼ストツパ 13 が配装されているとき、支持板 2 の上面と薬液容器 8 との間にほぼ 2 mm の間隙部 16 が形成される。したがって、この場合には、注射針 5 の刺部 6 の先端は、皮張体 15 の下端開口部より若干内方に位置される。

注入に際しては、カバー兼ストツパ 13 を支持板 2 と押圧体 12 との間から外し、皮張体 15 の下端開口縁部を皮膚面 14 に押し当てる。一方、薬液容器 8 の下端縁が支持板 2 の上面に担持され

8

るとともに刺部 6 が皮張体 15 から突出される。

したがって、押圧体 12 に押圧力を加えれば、注射針 5 の針 6 が前記の各実施例の場合と同様に、皮下に刺し込まれ液注される。上記の実施例は、皮張体 15 を支持板 2 に対して固定した場合を説明したが、支持板 2 と皮張体 15 とを相対的に可動し得る構造としてもよい。

更に、第 8 図に示した実施例について説明すると、この実施例においては、支持板 2、流通孔 3 及び注射針 5 については、前記第 1 図に示した実施例と同じ構造になっている。支持板 2 の上面には、流通孔 3 を包囲して半球状の薬液容器 8 が取付けてある。薬液容器 8 は例えばポリプロピレン等の合成樹脂材料から形成され、この内容積は、前記第 1 図に示した薬液容器 8 と同様に 1~10 μℓ の薬液を収容できる大きさになっている。上記半球状の薬液容器 8 を包囲してドーム状をなす押圧体 12 が、支持板 2 の上面に対して取付けてある。この押圧体 12 のドーム状の弾性体の中には、気体、通常空気を保持している。この押圧体 12 は、合成樹脂、ゴム等の弾性材料により形成されている。17、18 はカバーであり、断面形状が半球状に形成してある。カバー 17、18 はその開口縁部が支持板 2 の上下面に形成した係合凹所に係脱可能可能に取付けられる。上記の場合において、支持板 2 の上面に薬液容器 8 を包囲して取付けられる押圧板 12 内の空気は、生体内に注入されるものではないため、清浄な空気を充填する必要はない。押圧体 12 内の空気は単に薬液容器 8 の外面を加圧するために利用されるものであり、従つて、例えば支持板 2 上に薬液容器 8 を形成した後、該薬液容器 8 を包囲するように押圧体 12 が空気を含んだ状態で密着せしめればよい。

注射器に薬液を充填するには、カバー 17、18 を支持板 2 から外す。次に、支持板 12 を支持板 2 の上面側方向に押圧し、薬液容器 8 を加圧する。この状態下において、注射針 5 をバイアル罐等に挿入し、押圧板 12 を押圧を解除すれば、押圧板 12 及び薬液容器 8 の復元により、薬液容器 8 内が陰圧となり、薬液が注射針を介して吸い込まれる。次に、注入を行うには、第 1 図に示した注射器の場合で説明したと同様に、支持板 2 の一端縁 2 a を皮膚面 14 に押し当て、注射器すべ

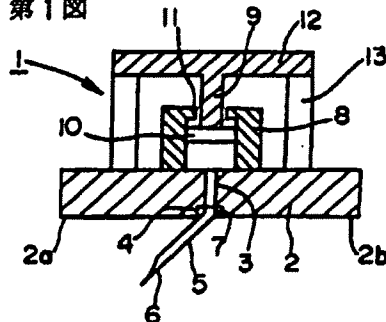
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部分を皮張させ、そして、そのまま支持板2の他端縁2b側を皮膚面14に近づけ、注射針5の刺部8を皮下に刺し込むと共に押圧板12の全体を中心部方向に押し込む。すると、薬液容器8は、その全周面から加圧作用を受けてドーム状の弾性

体の中に存在する気体により圧縮されて、容器内の薬液が皮下に液注されることになる。  
更に、上記第8図に示した実施例の変形例として第9図に示されるように構成することもできる。この実施例においては、薬液の押し出す押圧体12が、スポンジ、ゴムその他これに類する弾性材料によりドーム状の中実形状に形成されている。もちろん、押圧体12と薬液容器8の外周面との間には、僅かな隙間部が形成してある。したがって、この実施例の場合には、押圧体12を加圧すれば、その加圧力が薬液容器8の外周面に付加されるとともに押圧体12が隙間部の方向に加圧変形されるので、薬液容器8が押圧されて、液注が行われる。

本発明は、以上詳細に説明したように、10~100 $\mu$ 径の注射針が支持板の下側に45°~90°の傾斜角度を保って設けられ、かつ、この注射針は支持板に上部側に設けられた1~10 $\mu$ ℓの内容積を持つ薬液容器内と連通され、そして薬液容器内の規定量の薬液を液注するには、先ず注射すべき皮膚面を支持板で皮張させ、該皮張下において極細の注射針で皮下に液注する構成である。従つて、本発明の注射器によれば、注射すべき皮膚面を一々指先で突張つて注射針の刺部が入り易くする等の面倒な操作を必要としない。又、注射針は、10~100 $\mu$ 径の極細であるため、殆んど痛みを感じさせることなく皮下または皮内に刺し込むことができ、しかも、注射針が必要以上に挿入されること

第1図



10

がないので、筋注薬害等を起因するおそれはなく、極めて安全に使用できる。更に、薬液も1~10 $\mu$ ℓと薬液容器で規制収容されるため、過剰に注入してしまうおそれはない。特に、構造的にも簡単でかつコンパクトであるため、安価に提供できるので経済的にも有利であり、デイスポーザブル式に使用することが可能となる。また、本発明の注射器は、前記で説明したように、液注の際に危険性を伴わないことから、患者が一般家庭で簡単に液注できる。このため、今までのように、病院に連日行つて注射するの必要がなくなる等の利点もある。

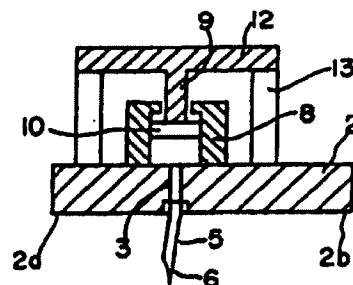
なお、本発明注射器の主要部である10~100 $\mu$ 径の注射針と、1~10 $\mu$ ℓの内容積を有する薬液容器を有する構造であれば、実施例の細部構造にわたつて種々の変形や変更を加えることができる。

#### 図面の簡単な説明

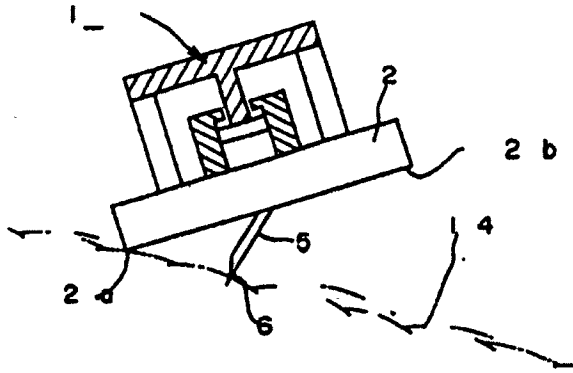
図面は本発明の数個の実施例を示したものである。第1図は第1実施例による注射器の拡大断面図、第2図および第3図は注入を行う状態の作用説明図、第4図は第2実施例による注射器の拡大断面図、第5図は第3実施例による注射器の拡大断面図、第6図は第4実施例による注射器の拡大断面図、第7図は第5実施例による注射器の拡大断面図、第8図は第6実施例による注射器の拡大断面図、第9図は第7実施例による注射器の拡大断面図である。

符号の説明、2は支持板、2aは支持板の一端縁、2bは支持板の他端縁、5は注射針、8は刺部、8は薬液容器、9はピストンロッド10はピストン、12は押圧板、14は皮膚面、15は皮張体である。

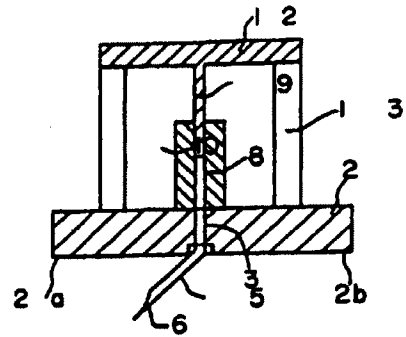
第5図



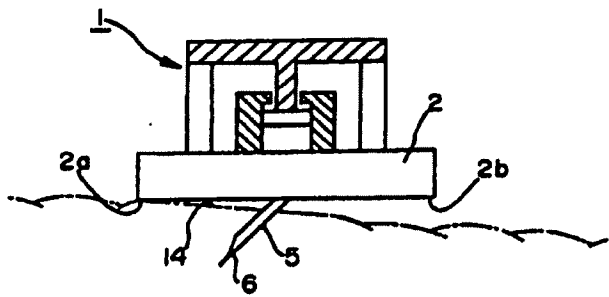
第 圖



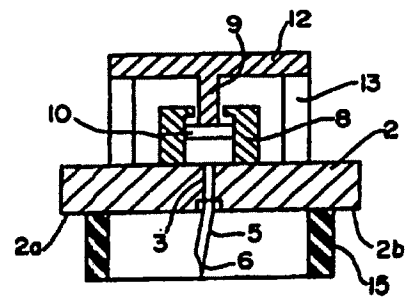
第 4 圖



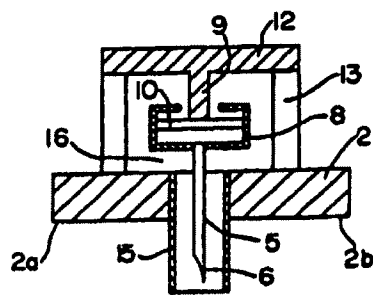
第 3 圖



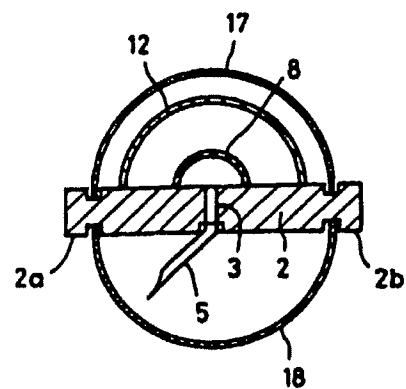
第 6 圖



第 7 圖



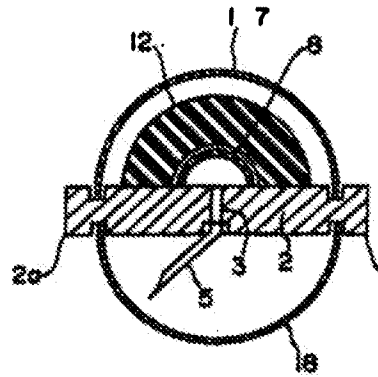
第 8 圖



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第 9 図





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D1 A

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Inventors: Ryohei HORI and Katsuhiko OKUMURA

Applicant: Toyo Jozo Kabushiki Kaisha

Title of the Invention: Microsyringe

[CLAIMS]

1. A microsyringe comprising on an upper side of a substructure a liquid medicine container with a capacity of 1 to 10  $\mu$ l and a plunger for expelling a specified amount of liquid medicine held in said liquid medicine container, and a 10 to 100  $\mu$ m-diameter syringe needle secured to the underside of said substructure at an angle of 45° to 90° with respect to said substructure and communicating with said liquid medicine container.
2. The microsyringe of Claim 1, wherein said liquid medicine container is in the form of a cylinder and said plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container comprises a piston that is slidably fitted inside said liquid medicine container and a plunger plate secured to said piston by means of a piston rod.
3. The microsyringe of Claim 1, wherein said liquid medicine container mounted on an upper side of said substructure is formed of an elastic material.
4. The microsyringe of Claim 3, wherein said liquid medicine container formed of an elastic material is semicircular in cross section.
5. The microsyringe of Claim 3, wherein the plunger for

expelling a specified amount of liquid medicine held inside said liquid medicine container is made of an elastic material having a shape of dome provided on an upper side of said substructure so as to enclose said liquid medicine container, said plunger containing a gas on the inside of said dome-shaped elastic material.

6. The microsyringe of Claim 3, wherein the plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container made of an elastic material is formed of a dome-shaped solid elastic material provided on said substructure so as to enclose said liquid medicine container with a small gap between said plunger and said liquid medicine container.

7. A microsyringe comprising on an upper side of a substructure a liquid medicine container with a capacity of 1 to 10  $\mu$ l and a plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container, a 10 to 100  $\mu$ m-diameter syringe needle secured to the underside of said substructure at an angle of 45° to 90° with respect to said substructure and communicating with said liquid medicine container, and a skin stretcher formed of sponge, rubber or other similar elastic materials that surrounds said syringe needle with some room between said syringe needle and said skin stretcher.

8. The microsyringe of Claim 8, wherein said skin stretcher is in a form of a sleeve formed of metallic material, hard paper, or hard synthetic resin material.

9. The microsyringe of Claim 8, wherein said skin stretcher in the form of a sleeve is provided so it is slidable with respect to the substructure.

10. The microsyringe of Claim 7, wherein said liquid medicine

container mounted on an upper side of said substructure is formed of an elastic material.

11. The microsyringe of Claim 10, wherein said liquid medicine container formed of an elastic material is semicircular in cross section.

12. The microsyringe of Claim 10, wherein the plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container made of an elastic material is formed of a dome-shaped elastic material provided on an upper side of said substructure so as to enclose said liquid medicine container, said plunger containing a gas on the inside of said dome-shaped elastic material.

13. The microsyringe of Claim 10, wherein said plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container made of an elastic material is formed of a dome-shaped solid elastic material provided on said substructure so as to enclose said liquid medicine container with a small gap between said plunger and said liquid medicine container.

[DETAILED DESCRIPTION OF THE INVENTION]

[TECHNICAL FIELD OF THE INVENTION]

The present invention relates to a microsyringe suitable for injecting minute quantities of liquid medicines comprising physiologically active substances such as calcitonin and prostaglandin.

[PRIOR ART]

Physiologically active substances such as calcitonin and prostaglandin, when administered to the human body by injection, are delivered in extremely minute quantities (1 to 10  $\mu$ l). Pharmaceuticals of this sort have been injected by means of a syringe that, for example, has a piston detachably fitted in

a cylinder that has a syringe needle at its tip. Using such a syringe, however, the injection of minute quantities in a range of 1 to 10  $\mu$ l was impossible because of large dimensions of the syringe body itself or a large diameter of such a syringe needle (500 to 2500  $\mu$ m). Thus, there were disadvantages involved in using such a conventional syringe: liquid medicines for injection had to be diluted, increasing the injection quantities to about 1 ml; the injections were accompanied with pain that was felt under the skin or at other similar parts because of the large diameter of the syringe needle; and before inserting the syringe needle under the skin or into other like parts of the body, the region of a patient's skin surface where the injection is to be given had to be stretched with finger tips of the hand that does not hold the syringe every time the injection is given in order to facilitate the insertion of the syringe needle tip into or through the skin.

Further, the tip of such a conventional syringe needle is inserted into the human body by a depth that a physician or the like judges to be appropriate according to his/her experience. Thus, the insertion can be actually made to a depth that passes by a desirable location of injection by as much as 0.5 to 3 cm.

[PROBLEMS TO BE SOLVED BY THE INVENTION]

As described above, the syringe needle tip is inserted in the skin deeper than the target injection location typically by a distance of 0.5 cm to 3 cm though the distance may vary depending on whether the injection is hypodermic, intradermal or intramuscular. This could result in injuring the blood vessel system, nervous system, hypodermic tissues and the like, possibly causing harmful drug effects due to intramuscular injections such as constriction of quadriceps femoris. Thus the injections using such a conventional syringe have been associated with potentially grave dangers.

The inventors of the present invention conducted intensive

researches in an effort to solve such conventionally encountered problems and succeeded in developing a syringe intended for use in administering physiologically active substances such as calcitonin and prostaglandin that are typically delivered in minute quantities.

An object of the invention is to provide a microsyringe capable of hypodermically or intradermally administering a liquid medicine of physiologically active substances in minute quantities (1 to 10  $\mu$ l) almost painlessly, whereby the possibility of injuring the hypodermic tissues or producing harmful drug effects such as destruction is eliminated with certainty.

[MEANS TO SOLVE THE PROBLEMS]

As a means to solve the problems described above, the present invention provides a microsyringe comprising on a substructure a liquid medicine container with a capacity of 1 to 100  $\mu$ l and a plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container, and a 10 to 100  $\mu$ m-diameter syringe needle secured to the underside of said substructure at an angle of 45° to 90° with respect to said substructure and communicating with said liquid medicine container. The present invention further provides a microsyringe comprising on a substructure a liquid medicine container with a capacity of 1 to 10  $\mu$ l and a plunger for expelling a specified amount of liquid medicine held inside said liquid medicine container, a 10 to 100  $\mu$ m-diameter syringe needle mounted under said substructure at an angle of 45° to 90° with respect to said substructure and communicating with said liquid medicine container, and a skin stretcher formed of sponge, rubber or other similar elastic materials that surrounds said syringe needle with some room between said syringe needle and said skin stretcher.

[EFFECTS OF THE INVENTION]

A part of the peripheral edge of the substructure is pressed against the neighborhood of a location on the skin surface where an injection is to be given and a part of the peripheral edge on the opposite side of the substructure is moved closer toward the skin surface, thus stretching the skin surface region where the injection is to be given. Keeping that skin surface region so stretched, the substructure is brought still closer to the skin surface until the insertion tip of the extremely thin syringe needle secured to said substructure is inserted into the hypodermis or dermis. Thus, according to the syringe of the invention, one need not take the trouble of preparing the skin every time an injection is delivered in order to facilitate the insertion of the syringe needle tip by, for example, using finger tips to stretch the skin surface region where the injection is to be given.

Several embodiments of the present invention will be described below in detail. It is noted that nothing in the description will limit the scope of the invention.

#### A FIRST PREFERRED EMBODIMENT

A syringe 1 shown in Fig. 1 through Fig. 3 according to the invention comprises a substructure 2. The substructure 2 may be in the form of a disc made, for example, of a metallic material, a synthetic resin material or the like. The substructure 2 may be designed, by way of example, to have a diameter of 1 to 2 cm and a thickness of 2 to 5 mm to provide easy handling. The substructure need not necessarily be of a discoid shape as in the case of this embodiment but may be formed into any other shape such as one with angles or an oval shape, as desired.

At the center of the substructure 2 is formed a passage 3 with a diameter of 0.05 to 0.1 mm. A fitting recess 4 is provided in the bottom surface of the substructure 2. The end 7 of a syringe needle 5 opposite to the insertion tip 6 is directly inserted in the passage 3 and secured therein. Needless to say,

the end 7 may be fixed by any suitable means other than by insertion. The syringe needle 5, made of a metallic material such as stainless steel or synthetic resin material, is formed into a minuscule syringe needle with a diameter of 10 to 100  $\mu\text{m}$  and a length of 1 to 5 mm. It is important that the syringe needle 5 be secured to said substructure 2 so the angle the syringe needle 5 forms with the bottom surface of the substructure 2 is kept at  $45^\circ$  or more, preferably at an angle of  $60^\circ$  to  $90^\circ$ . This geometry, i.e., the angle at which the syringe needle 5 is attached to the substructure 2, and the extremely thin configuration with a diameter of 10 to 50  $\mu\text{m}$  allow the insertion tip 6 of the syringe needle 5 to cut into the skin surface causing little pain and smoothly advance deeper into the hypodermic or intradermal region.

On the upper surface of the substructure 2, a liquid medicine container 8 is provided so as to surround the passage 3. The liquid medicine container 8 should be large enough to hold a liquid medicine in an amount of 1 to 10  $\mu\text{l}$ . The container 8 accommodates an aliquot of a solution of a physiologically active substance such as calcitonin and prostaglandin. A piston rod 9 provided in the liquid medicine container 8 has at its tip a piston 10 formed of an elastic material such as silicon rubber. A stopper member 11 formed at the opening rim of the liquid medicine container 8 blocks the escape of the piston 10 from the liquid medicine container 8. The piston rod 9 is integrated with a plunger 12 that is formed of a metallic material or a synthetic resin. The numeral 13 in the drawing indicates a cover/stopper that has an opening formed by cutting out a part of the cover/stopper in an axial direction. The opening is slightly larger than the outer diameter of the liquid medicine container. Thus the liquid medicine container 8 can be readily withdrawn or put back through this opening whereas the cover/stopper 13 is detachably installed between the substructure 2 and the plunger 12.

Next, the use of the syringe will be described. First, the cover/stopper 13 is removed from between the substructure 2 and the plunger 12 and the plunger 12 is depressed downwardly as seen in Fig. 1. The insertion tip 6 of the syringe needle 5 is then inserted into a vial or the like container that contains a physiologically active substance vessel [apparently "substance vessel" should be just "substance"] and the plunger 12 is lifted in the opposite direction, whereon the piston 10 causes a specified quantity of a liquid medicine to be filled in the liquid medicine container 8 through the syringe needle 5.

To execute the hypodermic or intradermal insertion into the human body, a part of the peripheral edge of the substructure 2, i.e., an edge part 2a in the direction of which the insertion tip 6 of the syringe needle 5 is oriented is pressed against the neighborhood of the location on a skin surface 14 at which the injection should be administered (see Fig. 2). The opposite edge part 2b of the substructure 2 is brought closer to the skin surface 14 by pivoting the substructure 2 about the fulcrum, i.e., the position at which the substructure 2 is pressed against the skin surface 14 (see Fig. 3). Thus, the edge part 2a of the substructure 2 causes the skin surface 14 to stretch further outwardly from the edge part 2a.

Consequently, the region of the skin surface 14 where the insertion is to be delivered is stretched and the insertion tip 6 of the syringe needle 5, tilted at an appropriate angle, makes a cut in the skin surface 14, smoothly entering the ~~hypodermic or intradermal~~ region. Simultaneously, the plunger 12 is pressed smoothly to depress the piston 10 downwardly in the liquid medicine container 8 and force the liquid medicine held inside the liquid medicine container 8 to flow out through the passage 3 and into the hypodermic or intradermal region via the syringe needle 5. The insertion tip 6 of the syringe needle 5 enters the skin surface 14 at an angle with respect to the skin surface



14 as the edge part 2b of the substructure 2 is brought closer to the skin surface 14 by pivoting the syringe about the edge part 2a because the syringe needle 5 is secured to the substructure 2 at an appropriate angle.

Therefore the syringe needle 5 only enters the epidermis by a depth of not greater than 3 mm (1 to 2 mm in practice) and can never go deeper in the ~~internal~~ <sup>subcutaneous</sup> region than is necessary, providing utmost safety in handling. Inserting the tilted, extremely thin syringe needle 5 into the hypodermis at an angle with respect to the skin surface that is kept stretched by the substructure 2 as described above is comparable to the case of a mosquito conducting blood sucking, which also causes little pain: the mosquito uses its legs to hold and stretch the skin surface and then drive its fine, pointed sting into the hypodermis.

Another embodiment of the invention illustrated in Fig. 4 is similar to the first embodiment shown in Fig. 1, the difference being that the liquid medicine container 8 of the embodiment shown in Fig. 4 has the same inner diameter as the passage 3. Consequently, the piston 10 has a different shape from that provided in the embodiment of Fig. 1. The liquid medicine container 8 in this second embodiment is also sufficiently large to hold 1 to 10  $\mu$ l of a liquid medicine. The syringe according to the second embodiment of the invention operates in the same manner as that shown in Fig. 1 and therefore will not be described. Another embodiment of the invention illustrated in Fig. 5 is similar to the first embodiment of Fig. 1, the difference being that the syringe needle 5 is positioned on the side of the substructure 2 where the edge part 2a is located rather than at the center of the substructure 2, and mounted at an angle that is maintained at 80° to 90°.

In still another embodiment of the invention, the syringe illustrated in Fig. 6 is different from that of Fig. 1 in that

a skin stretcher 15 formed of sponge, rubber, flexible synthetic resin or other similar materials is provided on the engaging surface of the substructure 2 so as to enclose a syringe needle 5. The skin stretcher 15 preferably has a shape that broadens progressively toward one end, i.e., a shape that is trunconical in cross-section. When the skin stretcher 15 is placed in contact with the skin surface 14 and the plunger 12 is depressed to deliver an injection, the region of the skin surface where the injection is to be given is stretched by the elastic force of the skin stretcher 15. Thus the insertion tip 6 of the syringe needle 5 is inserted smoothly into the hypodermis as in the case of the first embodiment shown in Fig. 1. The skin stretcher 15 may be provided with slits at appropriate intervals in the circumferential direction to enhance its elasticity.

A syringe according to yet another embodiment illustrated in Fig. 7 differs from that shown in Fig. 1 in that the syringe needle 5 is integrated with the liquid medicine container 8 and that a skin stretcher 15 is also provided. The skin stretcher 15 is formed of a metallic material, a hard synthetic resin material or the like. The skin stretcher 15 has a hollow, cylindrical shape and is disposed such that the brim of its upper end is flush with the upper surface of the substructure 2. The skin stretcher 15 accommodates the syringe needle 5 that is integrated at its upper end with the liquid medicine container 8, with some room around the syringe needle 5. The liquid medicine container 8 generally has a dish-like shape in cross section and accommodates a piston 10 and a piston rod 9 with the same structures as those of the embodiment shown in Fig. 1. The piston rod 9 is unitarily provided with a plunger 12. The syringe needle in this embodiment forms an angle of about  $90^\circ$  with the underside of the substructure 23 [23 apparently should be 2]. A cover/stopper 13 is detachably provided between the substructure 2 and the plunger 12 as in the embodiment of Fig. 1. With the cover/stopper 13 mounted, there is a space 16 of about 2 mm between the upper surface of the substructure

2 and the liquid medicine container 8. Thus, the insertion tip 6 of the syringe needle 5 stops slightly short of the lower end of the skin stretcher 15.

To perform an injection, the cover/stopper 13 is removed from between the substructure 2 and the plunger 12, and the rim of the lower opening end of the skin stretcher 15 is pressed against the skin surface 14. Meanwhile, the lower end rim of the liquid medicine container 8 is borne by the upper surface of the substructure 2 and the insertion tip 6 sticks out from the skin stretcher 15.

Thus, depressing the plunger 12 will cause the insertion tip 6 of the syringe needle 5 to be inserted beneath the skin in much the same way as with the preceding embodiments, accomplishing the injection. While the skin stretcher 15 in this embodiment is fixedly provided with respect to the substructure 2, the skin stretcher 15 and the substructure 2 may be provided such that they are movable in relation to each other.

Now another embodiment of the invention will be described referring to Fig. 8. This embodiment has the same structure as that of Fig. 1 with respect to the substructure 2, the passage 3 and the syringe needle 5. On the upper surface of the substructure 2 is provided a liquid medicine container 8 of a hemispherical shape that surrounds the passage 3. The liquid medicine container 8 may be made, for example, of a synthetic resin material such as polypropylene and can contain a liquid medicine in a quantity of 1 to 10  $\mu$ l as with the liquid medicine container 8 in the embodiment of Fig. 1. A dome-shaped plunger 12 is provided on the substructure 2 so as to surround said hemispherical liquid medicine container 8. This dome-shaped plunger 12 holds a gas inside, typically air. This plunger 12 is formed of an elastic material such as synthetic resin and rubber. Numerals 17 and 18 designate cover members each with

a semicircular cross section. The covers 17 and 18 are detachably mounted to the substructure 2 by engaging their opening rims with grooves formed in the upper and lower surfaces of the substructure 2. The air inside the plunger 12 that is mounted on an upper surface of the substructure 2 so as to enclose the liquid medicine container 8 is not injected into the body and thus need not be purified air. The air inside the plunger 12 is only used to apply pressure onto the outer surface of the liquid medicine container 8. Therefore, upon forming the liquid medicine container 8 on the substructure 2, the plunger 12 need only be mounted so as to enclose the liquid medicine container 8 with air inside the plunger 12.

To fill the syringe with a liquid medicine, the covers 17 and 18 are removed from the substructure 2. Then the substructure 2 [apparently plunger 12] is depressed toward the upper surface of the substructure 2 to apply pressure to the liquid medicine container 8. Keeping this state, the syringe needle 5 is inserted into a vial or the like. When the pressure applied to the plunger 12 is released, the plunger 12 and the liquid medicine container 8 are restored to their respective shapes to create negative pressure inside the liquid medicine container 8, causing the liquid medicine to be sucked in through the syringe needle. Next, to give an injection, as described above referring to the syringe of Fig. 1, one side of the substructure, i.e., the edge part 2a is pressed against the skin surface 14 to stretch the region of the skin surface where the injection should be delivered. Then, the other side, i.e., edge part 2b, is brought closer to the skin surface 14 and the insertion tip 6 of the syringe needle 5 is inserted into the hypodermis as the whole plunger 12 is pressed toward its center. Thus, the liquid medicine container 8 receives the pressure onto its whole area as the gas existing inside the dome-shaped elastic material compresses the container 8 and the liquid medicine inside the container is injected into the hypodermis.

The embodiment shown in Fig. 8 may be modified to provide a variation thereof as illustrated in Fig. 9, wherein the plunger 12 for expelling a liquid medicine has a solid, dome-shaped configuration formed of an elastic material such as sponge, rubber or the like. Needless to say, there is a small gap between the plunger 12 and the outer surface of the liquid medicine container 8. With this embodiment, therefore, when a pressure is applied to the plunger 12, the pressure is conveyed to the outer surface of the liquid medicine container 8 while at the same time the plunger 12 is deformed by the pressure toward the gap, which in turn depresses the liquid medicine container 8, thereby achieving the injection.

According to the present invention as described above in detail, the 10 to 100- $\mu$ m diameter syringe needle is mounted to the underside of the substructure at an angle of 45° to 90° and the syringe needle is in communication with the inside of the liquid medicine container with a capacity of 1 to 10  $\mu$ l provided on an upper side of the substructure. To inject a specified amount of liquid medicine held inside the liquid medicine container, the skin surface region where the injection is to be given is first stretched by the substructure and, keeping the skin thus stretched, a hypodermic injection is given by means of an extremely thin syringe needle. Thus, according to the syringe of the invention, one need not take the trouble of preparing the skin to facilitate the insertion of the syringe needle by, for example, using finger tips to stretch the skin surface region where the injection is to be delivered. Further, the extremely thin syringe needle in a range of 10 to 100  $\mu$ m enables almost painless hypodermic or intradermic insertions. In addition, the syringe needle is prevented from being inserted deeper than is necessary and, as such, the possibility of causing harmful drug effects due to accidental intramuscular injections is eliminated, providing utmost safety in use. Furthermore, there is also no risk of overdosing because the liquid medicine is held in a liquid medicine container only in

a specified quantity of 1 to 10  $\mu$ l as defined by the container. To be noted in particular is an advantage that the syringe according to the invention is compact and simple in design and as such can be provided at reasonable costs. This gives the syringe an economic advantage and it is possible to provide such syringe as a disposable article. Further, as described above, no risk is involved in the injection using the syringe of the invention and thus patients themselves may readily use the syringe to administer injections at home. This provides a further advantage that patients need not visit the hospital to receive injections, often almost on a daily basis.

It is to be understood that numerous modifications and variations may be made as to the structural details of the present invention, provided that the essential components, i.e., a syringe needle with a diameter of 10 to 100  $\mu$ m and a liquid medicine container with a capacity of 1 to 10  $\mu$ l be comprised.

[BRIEF DESCRIPTION OF THE DRAWINGS]

The drawings illustrate a few embodiments of the present invention. Fig. 1 is an enlarged cross section of a syringe according to a first embodiment of the invention. Fig. 2 and Fig. 3 are drawings for explaining the operation of an injection according to the invention. Fig. 4 is an enlarged cross section of a syringe according to a second embodiment. Fig. 5 is an enlarged cross section of a syringe according to a third embodiment. Fig. 6 is an enlarged cross section of a syringe according to a fourth embodiment. Fig. 7 is an enlarged cross section of a syringe according to a fifth embodiment. Fig. 8 is an enlarged cross section of a syringe according to a sixth embodiment. Fig. 9 is an enlarged cross section of a syringe according to a seventh embodiment.

Legend: Numeral 2 indicates a substructure, 2a an edge part of the substructure, 2b an edge part on the opposite side of the substructure, 5 a syringe needle, 6 an insertion tip, 8 a liquid

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medicine container, 9 a piston rod, 10 a piston, 12 a plunger,  
14 a skin surface and 15 a skin stretcher.

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[Note: All names, addresses, company names, and brand names are translated in the most common manner. Japanese language does not have singular or plural words unless otherwise specified with numeral prefix or general form of plurality suffix. The term "Shijiban" in the original document is translated as substructure in the English translation and "Oshiatsutai" in the original document is translated as plunger. The translator opted to use the term support plate for substructure and press body (in some cases, refers to press plate) for plunger for better accuracy. Translator's note]

#### [CLAIMS]

1. A microsyringe is composed by being equipped with a support plate, a liquid medicine container with an inner capacity of 1 to 10  $\mu$ l, and a press body that pushes out a specified amount of liquid medicine held in said liquid medicine container at an upper side of a support plate and a 10 to 100  $\mu$ m-diameter syringe needle that is secured to the underside of said support plate at an angle of 45° to 90° with respect to said support plate and communicatively connecting with inside of said liquid medicine container.
2. The microsyringe of Claim, wherein said liquid medicine container is in the form of a cylinder and said press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container comprises a piston that is slidably fitted inside said liquid medicine container and a press plate that is attached to said piston by means of a piston rod.
3. The microsyringe of Claim 1, wherein said liquid medicine container that is mounted on an upper side of said support plate is formed of an elastic material.
4. The microsyringe of Claim 3, wherein said liquid medicine container that is formed of an elastic material is shaped as a semispherical form in its cross section.
5. The microsyringe of Claim 3, wherein the press body that



pushes out a specified amount of liquid medicine held inside said liquid medicine container is made of an elastic material having a shape of dome that contains a gas present within the dome-shaped elastic body that is attached to an upper side of said support plate so as to enclose said liquid medicine container.

6. The microsyringe of Claim 3, wherein the press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container made of an elastic material is formed of a dome-shaped solid elastic material that is attached to said support plate so as to enclose said liquid medicine container with a small gap between said press body and said liquid medicine container.

7. A microsyringe is composed by being equipped with a liquid medicine container with a capacity of 1 to 10  $\mu$ l and a press body that pushes out a specified amount of liquid medicine held in said liquid medicine container at an upper side of a support plate, a 10 to 100  $\mu$ m diameter syringe needle that is secured to the underside of said support plate at an angle of 45° to 90° with respect to said support plate and communicatively connecting with inside of said liquid medicine container, and a skin stretcher that is formed of sponge, rubber, or other similar elastic materials that surrounds said syringe needle with some room between said syringe needle and said skin stretcher.

8. The microsyringe of Claim 8 [note, the numeral is illegible and it may represent 3, translator's note], wherein said skin stretcher is in a form of a sleeve formed of metallic material, hard paper, or hard synthetic resin material.

9. The microsyringe of Claim 8 wherein said skin stretcher in the form of a sleeve is attached so it is slidable with respect to the support plate.

10. The microsyringe of Claim 7, wherein said liquid medicine

container that is attached to an upper side of said support plate is formed of an elastic material.

11. The microsyringe of Claim 10, wherein said liquid medicine container that is formed of an elastic material is shaped as semispherical in its cross section.

12. The microsyringe of Claim item 10, wherein the liquid medicine container that is formed of an elastic material and the press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container are formed of a dome-shaped elastic material that contains a gas present within the dome-shaped elastic body that is attached to an upper side of said support plate so as to enclose said liquid medicine container.

13. The microsyringe of Claim 10, wherein said press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container that is made of an elastic material is formed of a dome-shaped solid elastic material provided on upper side of the support plate so as to enclose said liquid medicine container with a small gap between said press body and said liquid medicine container.

#### [DETAILED DESCRIPTION OF THE INVENTION]

#### [TECHNICAL FIELD OF THE INVENTION]

The present invention relates to a microsyringe that is suitable for injecting minute quantities of liquid medicine comprising physiologically active substance such as calcitonin and prostaglandin.

#### [PRIOR ART]

When administering physiologically active substances such as calcitonin and prostaglandin to the human body by injection, its necessary quantity of injection is extremely minute (1 to 10  $\mu$ l). Pharmaceuticals of this sort have been injected by means of a syringe that, for example, is of a piston-form detachably fitted in

a cylinder that has a syringe as its tip. Using such a syringe, however, the injection of minute quantities in a range of 1 to 10  $\mu$ l was impossible because of large dimensions of the syringe body itself or a large diameter of such a syringe needle (500 to 2500  $\mu$ ). Thus, there were disadvantages involved in using such a conventional syringe; and liquid medicines for injection had to be diluted, increasing the injection quantities to about 1 ml; and the injections were accompanied with pain that was felt under the skin or at other similar parts because of the large diameter of the syringe needles; and before inserting the syringe needle under the skin or into other like parts of the body, the region of a patient's skin surface where the injection is to be given had to be stretched with finger tips of the hand that does not hold the syringe every time the injection is given in order to facilitate the insertion of the syringe needle tip into or through the skin, and as been regarded as cumbersome.

Further, even during the insertion of tip of the syringe into the human body by a depth that a physician or the like judges to be appropriate according to his/her experience, current situation is that the insertion has been actually made to a depth that passes by a desirable location of injection by as much as 0.5 to 3 cm.

#### [PROBLEMS TO BE SOLVED BY THE INVENTION]

As described above, because the syringe needle tip is inserted in the skin deeper than the target injection location typically by a distance of 0.5 cm to 3 cm though the distance may vary depending on whether or not the injection is hypodermic, intradermal, or intramuscular, this could result in injecting the blood vessel system, nervous system, hypodermic tissues and the like as well as it is possible to cause harmful drug effects due to intramuscular injections such as constriction of quadriceps femoris to accompany possible grave dangers through use of conventional syringe.

The inventors of the present invention conducted intensive

researches in an effort to solve such conventionally encountered problems described above, and succeeded in developing a syringe intended for use in administering physiologically active substances such as calcitonin and prostaglandin that are typically delivered in minute quantities.

An objective of this invention is to provide a microsyringe capable of hypodermically or intradermally administering a liquid medicine of physiologically active substances in minute quantities (1 to 10  $\mu$ l) almost painlessly, whereby the possibility of injuring the hypodermic tissues or producing harmful drug effects such as destruction is eliminated with certainty.

#### [MEANS TO SOLVE THE PROBLEMS]

As a means to solve the various problems described above, the present invention provides a microsyringe that is composed by being equipped with a liquid medicine container with an inner capacity of 1 to 100  $\mu$ l and a press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container at an upper side of a support plate, and a 10 to 100  $\mu$ m-diameter syringe needle that is attached to the underside of said support plate at an angle of 45° to 90° with respect to said support plate and communicatively connecting with inside of said liquid medicine container. The present invention further provides a microsyringe that is composed by being equipped with a liquid medicine container with an inner capacity of 1 to 10  $\mu$ l and a press body that pushes out a specified amount of liquid medicine held inside said liquid medicine container at an upper side of a support plate, and 10 to 100  $\mu$ m-diameter syringe needle that is attached under said support plate at an angle of 45° to 90° with respect to said support plate and communicatively connecting with inside of said liquid medicine container, and a skin stretcher formed of sponge, rubber, or other similar elastic materials that surrounds said syringe needle with some room between said syringe needle and said skin stretcher.

#### [ACTIONS]

A part of one end of the support plate is pressed against the neighborhood of a location on the skin surface where an injection is to be given and the other end of the support plate is moved close in the direction toward the skin surface. Thus, stretching the skin surface region where the injection is to be given. Under a state of stretched skin, the insertion part of the extremely fine needle that is arranged on said support plate may be inserted into hypodermis or dermis by further bringing the support plate closer to the skin surface. Thus, according to the syringe of the present invention, one need not take the trouble of preparing the skin every time an injection is delivered in order to facilitate ease of insertion of the syringe needle tip by, for example, using finger tips to stretch the skin surface region where the injection is to be given.

Several embodiments of the present invention will be described below in detail. It is noted that nothing in the description will limit the scope of the invention.

#### CONSTITUTION OF THE FIRST PREFERRED EMBODIMENT

A syringe 1 shown in Fig. 1 through Fig. 3 according to the present invention is equipped with a support plate 2. The support plate 2 may be in the form of a disc made, for instance, of a metallic material, a synthetic resin material or the like. The support plate 2 may be selected, by way of example, to have a diameter of 1 to 2 cm and a thickness of 2 to 5 mm to provide ease of handling. The support plate need not necessarily be of a discoid shape as in the case of this embodiment but may be formed into any other shape such as one with angles or an oval shape, as desired.

At the center of the support plate 2 is formed a flow passage hole 3 with a diameter of 0.05 to 0.1 mm. A fitting recess [concave] 4 is provided in the bottom surface of the support plate 2. The end part 7 of a syringe needle 5 that is opposite to the insertion tip 6 is directly inserted in the flow passage hole 3 and secured therein. Needless to say,

this attachment may be fixed by any suitable means not limiting to by insertion. The syringe needle 5, made of a metallic material such as stainless steel or synthetic resin material, is formed into a micro-syringe needle with a diameter of 10 to 100  $\mu\text{m}$  and a length of 1 to 5 mm. It is important that the syringe needle 5 be secured to said support plate 2 so the angle of the syringe needle 5 forms with the bottom surface of the support plate 2 is kept at 45° or more, preferably, at an angle of 60° to 90°. This geometry, for instance, the angle at which the syringe needle 5 is attached to the support plate 2, and the extremely fine configuration with a diameter of 10 to 50  $\mu\text{m}$  allow the insertion tip 6 of the syringe needle 5 to cut into the skin surface causing hardly any pain and smoothly advance deeper into the hypodermic or intradermal region.

On the upper surface of the support plate 2, a liquid medicine container 8 is placed so as to surround the flow passage hole 3. The liquid medicine container 8 should be large enough to hold a liquid medicine in an amount of 1 to 10  $\mu\text{l}$ , and therefore, the liquid medicine container 8 contains specified amount of a liquid solution of a physiologically active substance such as calcitonin and prostaglandin. A piston rod 9 that is provided in the liquid medicine container 8 has at its tip a piston 10 formed of an elastic material such as silicon rubber. A stopper piece 11 formed at the opening rim of the liquid medicine container 8 blocks the escape of the piston 10 from the liquid medicine container 8. The piston rod 9 is integrated with a press body 12 that is formed of a metallic material or a synthetic resin. The number 13 in the drawing indicates a cover/stopper. This stopper 13 has an opening part that is formed by cutting out a part of the cover/stopper in an axial direction. The opening is slightly larger than the outer diameter of the liquid medicine container 8. Thus the liquid medicine container 8 can be readily withdrawn or put back through this opening whereas the cover/stopper 13 is detachably installed between the support plate 2 and the press body 12.

Next, the use of the syringe will be described. Firstly, the cover/stopper 13 is removed from between the support plate 2 and the press body 12, and the press body 12 is depressed downwardly as seen in Fig. 1. The insertion tip 6 of the syringe needle 5 is then inserted into a vial or the like that contains a physiologically active substance, and the press body 12 is lifted in the opposite direction, whereon the piston 10 causes a specified quantity of a liquid medicine to be filled in the liquid medicine container 8 through the syringe needle 5.

To execute the hypodermic or intradermal insertion into the human body, one end part of the support plate 2, for instance, an end part 2a in the direction of which the insertion tip 6 of the syringe needle 5 is oriented is pressed against the neighborhood of the location on a skin surface 14 at which the injection should be administered (see Fig. 2). The other end 2b of the support plate 2 is brought closer to the skin surface 14 by pivoting the position that is pressed against as a fulcrum, for instance, the position at which the support plate 2 is pressed against the skin surface 14 (see Fig. 3). Thus, the end part 2a of the support plate 2 causes the skin surface 14 to stretch further outwardly from the one end part 2a.

Consequently, the region of the skin surface 14 where the insertion is to be delivered is stretched and the insertion tip 6 of the syringe needle 5, tilted at an appropriate angle, makes a cut in the skin surface 14, smoothly entering as it is. Simultaneously, the press body 12 is pressed smoothly to depress the piston 10 downwardly in the liquid medicine container 8 and force the liquid medicine held inside the liquid medicine container 8 to flow out through the flow passage hole 3 into the hypodermic or intradermal region via the syringe needle 5. The insertion tip 6 of the syringe needle 5 enters the skin surface 14 at an angle with respect to the skin surface

14 at the end part 2b of the support plate 2 is brought closer to the skin surface 14 by pivoting the syringe about the end part 2a because the syringe needle 5 is secured to the support plate 2 at an appropriate angle.

Therefore, the syringe needle 5 only enters the epidermis by a depth of 3 mm or less (1 to 2 mm in an actual sense) and presents no concern over entering deeper intracutaneously than is necessary to provide utmost safety in handling. Inserting the tilted, extremely fine syringe needle 5 into the hypodermis at an angle with respect to the skin surface that is kept stretched by the support plate 2 as described above is comparable to the case of a mosquito conducting blood sucking [action], which also causes hardly any pain; the mosquito uses its legs to hold and stretch the skin surface first and then, drives its fine, pointed sting into the hypodermis.

Another embodiment of the present invention illustrated in Fig. 4 is similar to the first embodiment shown in Fig. 1, the difference being that the liquid medicine container 8 of the embodiment shown in Fig. 4 has the same inner diameter as the flow passage hole 3. Consequently, the piston 10 that is inserted to this liquid medicine container 8 has a different shape from that provided in the embodiment of Fig. 1. It goes without saying that liquid medicine container 8 in this second embodiment is selected to be as such size to sufficiently large to hold 1 to 10  $\mu$ l of a liquid medicine. The syringe according to the second embodiment of the invention operates in the same manner as that shown in Fig. 1, and therefore, will not be described. Another embodiment of the present invention illustrated in Fig. 5 is similar to the first embodiment of Fig. 1, the difference being that the syringe needle 5 is positioned at the side of one end of the support plate 2 where the end part 2a is located rather than at the center of the support plate 2, and is attached at an angle that is maintained at 80° to 90°.

In still another embodiment of the present invention, the syringe illustrated in Fig. 6 is different from that of Fig. 1 in that



a skin stretcher 15 formed of sponge, rubber, flexible synthetic resin, or other similar materials is provided on the engaging surface of the support plate 2 so as to enclose the syringe needle 5. The skin stretcher 15 preferably has a shape that broadens progressively toward one end, for instance, a shape of a bugle form in its cross section. When the skin stretcher 15 is placed in contact with the skin surface 14 and the press body 12 is depressed to deliver an injection, the region of the skin surface where the injection is to be given is stretched by the elastic force of the skin stretcher 15, and thus the insertion tip 6 of the syringe needle 5 is inserted smoothly into the hypodermis as in the case of the first embodiment shown in Fig. 1. The skin stretcher 15 described above may be provided with slits at appropriate intervals in the circumferential direction to enhance its elasticity.

A syringe according to yet another embodiment illustrated in Fig. 7 differs from that shown in Fig. 1 in that syringe needle 5 is integrated with the liquid medicine container 8 and that a skin stretcher 15 is also provided. The skin stretcher 15 is formed of a metallic material, a hard synthetic resin material or the like. The skin stretcher 15 has a follow, cylindrical shape and is disposed such that the brim of its upper end is flush with the upper surface of the support plate 2. The skin stretcher 15 accommodates the syringe needle 5 that is integrated at its upper end with the liquid medicine container 8, with some room around the syringe needle 5. The liquid medicine container 8 generally has a dish-like shape in its cross section and accommodates a piston 10 and a piston rod 9 with the same structures as those of the embodiment shown in Fig. 1. The piston rod 9 is integrated with the press body 12. The syringe needle in this embodiment forms an angle of about 90° with the underside of the support plate 23 [note: 23 apparently should be 2, translator's note]. A cover/stopper 13 is detachably provided between the support plate 2 and the press body 12 as in the embodiment of Fig. 1. With the cover/stopper 13 mounted, there is a space 16 of about 2 mm between the upper surface of the support plate

2 and the liquid medicine container 8. Thus, the insertion tip 6 of the syringe needle 5 stops at slightly inner side of the lower end opening of the skin stretcher 15.

To perform an injection, the cover/stopper 13 is removed from between the support plate 2 and the press body 12, and the rim of the lower opening end of the skin stretcher 15 is pressed against the skin surface 14. Meanwhile, the lower end rim of the liquid medicine container 8 is borne by the upper surface of the support plate 2 and the insertion tip 6 sticks out from the skin stretcher 15.

Thus, when the press body 12 is pressed, it causes the insertion tip 6 of the syringe needle 5 to be inserted to inject liquid beneath the skin in much the same way as with the preceding embodiments, accomplishing the injection. Although above described embodiment explains the case when the skin stretcher 15 is fixed to the support plate 2, the skin stretcher 15 and the support plate 2 may be provided such that they are movable in relation to each other.

Now, when another embodiment of the present invention is described referring to Fig. 8, this embodiment has the same structure as that of Fig. 1 with respect to the support plate 2, the flow passage flow hole 3 and the syringe needle 5. On the upper surface of the support plate 2, a liquid medicine container 8 of a hemispherical shape that surrounds the flow passage hole 3 is attached. The liquid medicine container 8 may be made, for example, of a synthetic resin material such as polypropylene and its inner capacity can contain a liquid medicine in a quantity of 1 to 10  $\mu$ l as with the liquid medicine container 8 in the embodiment of Fig. 1. A dome-shaped press body 12 is provided on an upper surface of the support plate 2 so as to surround said hemispherical liquid medicine container 8. This dome-shaped press body 12 holds a gas inside, typically, air. This press body 12 is formed of an elastic material such as synthetic resin and rubber. Numerals 17 and 18 designate cover members each with

a semispherical cross section. The covers 17 and 18 are detachably mounted to the support plate 2 by engaging their opening rims with concaves formed in the upper and lower surfaces of the support plate 2. According to above description, the air inside the press body 12 that is mounted on an upper surface of the support plate 2 so as to enclose the liquid medicine container 8 is not injected into the body and thus need not be of a purified air. The air inside the press body 12 is only used to apply pressure onto the outer surface of the liquid medicine container 8 on the support plate 2, for instance, the press body 12 need only be mounted so as to enclose the liquid medicine container 8 with air inside the press body 12.

To fill the syringe with a liquid medicine, the covers 17 and 18 are removed from the support plate 2. Then the support plate 12 [note: apparently press body 2, translator's note] is depressed toward the upper surface of the press body 2 to apply pressure to the liquid medicine container 8. Keeping this state, the syringe needle 5 is inserted into a vial or the like, and when the pressure applied to the press plate 12 is released, the press plate 12 and the liquid medicine container 8 are restored to their respective shapes to create negative pressure inside the liquid medicine container 8, causing the liquid medicine to be sucked in through the syringe needle. Next, to give an injection, as described above referring to the syringe of Fig. 1, one end side of the support plate, for instance, the end part 2a of the support plate 2 is pressed against the skin surface 14 to stretch the region of the skin surface where the injection should be delivered, and then, the other side, for instance, end part 2b of the support plate 2 is brought closer to the skin surface 14 and the insertion tip 6 of the syringe needle 5 is inserted into the hypodermis as the whole press plate 12 is pressed toward its center. Thus, the liquid medicine container 8 received the pressure onto its whole area as the gas existing inside the dome-shaped elastic material compresses the container 8 and the liquid medicine inside the container is injected into the hypodermis.

The embodiment shown in the Fig. 8 may be modified to provide a variation thereof as illustrated in Fig. 9, wherein the press body 12 that pushes out a liquid medicine has a solid dome-shaped configuration formed of an elastic material such as sponge, rubber, or the like. Needless to say, there is a small gap between the press body 12 and the outer circumferential surface of the liquid medicine container 8. With this embodiment, therefore, when a pressure is applied to the press body 12, the pressure is conveyed to the outer circumferential surface of the liquid medicine container 8 while at the same time, the press body 12 is deformed by the pressure toward the gap, which in turn depresses the liquid medicine container 8, thereby achieving the injection of liquid.

According to the present invention as described above in detail, the 10 to 100  $\mu\text{m}$  diameter syringe needle is mounted to the underside of the support plate at an angle of  $45^\circ$  to  $90^\circ$  and the syringe needle is in communicatively connected with the inside of the liquid medicine container with an inner capacity of 1 to 10  $\mu\text{l}$  provided on an upper side of the support plate, and to inject a specified amount of liquid medicine held inside the liquid medicine container, the skin surface region where the injection is to be given is first stretched by the support plate and keeping the skin thus stretched, a hypodermic injection is given by means of an extremely fine syringe needle, and thus, according to the syringe of the present invention, one need not take the trouble of preparing the skin to facilitate the insertion of the syringe needle by, for example, using finger tips to stretch the skin surface region where the injection is to be delivered. Further, the extremely fine syringe needle in a range of 10 to 100  $\mu\text{m}$  enables almost painless hypodermic or intradermic insertion. In addition, the syringe needle is prevented from being inserted deeper than is necessary and, as such, the possibility of causing harmful drug effects due to utmost safety in use. Furthermore, there is also no risk of overdosing because the liquid medicine is held in a liquid medicine container only in

a specified quantity of 1 to 10  $\mu$ l as defined by the container. To be noted in particular is an advantage that the syringe according to the present invention is compact and simple in design and as such can be provided at reasonable costs, this gives the syringe an economic advantage and it is possible to provide such syringe as a disposable article. Further, as described above, no risk is involved in the injection using the syringe of the present invention and thus patients themselves may readily use the syringe to administer injections at home. This provides a further advantage that patients need not visit the hospital to receive injections, often almost on a daily bases.

It is to be understood that numerous modifications and variations may be made as to the structural details of the present invention, provided that the essential components, for instance, a syringe needle with a diameter of 10 to 100  $\mu$ m and a liquid medicine container with an inner capacity of 1 to 10  $\mu$ l be observed.

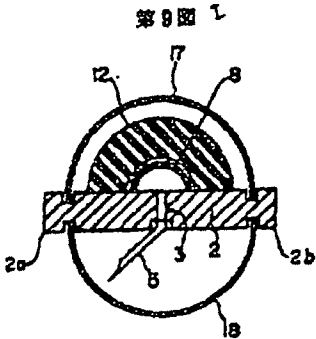
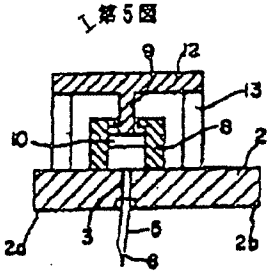
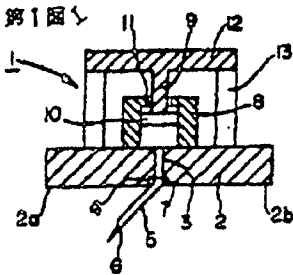
#### [BRIEF DESCRIPTION OF THE DRAWINGS]

The drawings illustrate a few embodiments of the present invention. Fig. 1 is an enlarged cross section of a syringe according to a first embodiment of the present invention; Fig. 2 and Fig. 3 are drawings for explaining the operation of an injection according to the present invention; Fig. 4 is an enlarged cross section of a syringe according to a second embodiment; Fig. 5 is an enlarged cross section of a syringe according to a third embodiment; Fig. 6 is an enlarged cross section of a syringe according to a fourth embodiment; Fig. 7 is an enlarged cross section of a syringe according to a fifth embodiment; Fig. 8 is an enlarged cross section of a syringe according to a sixth embodiment; and Fig. 9 is an enlarged cross section of a syringe according to a seventh embodiment.

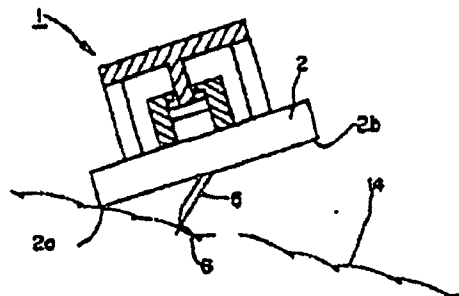
Legend: Numeral 2 indicates a support plate, 2a an end part of the support plate, 2b an end part of the opposite side of the support plate, 5 a syringe needle, 6 an insertion tip, 8 a liquid

medicine container, 9 a piston rod, 10 a piston, 12 a press plate, 14 a skin surface, and 15 a skin stretcher.

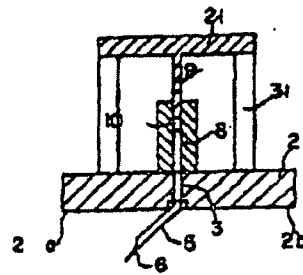
[I: Figure]



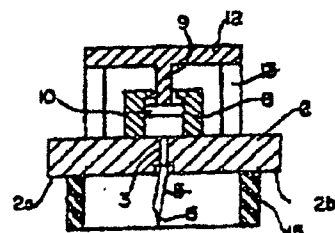
第 2 圖



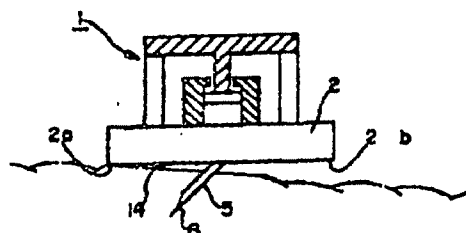
第 1 圖



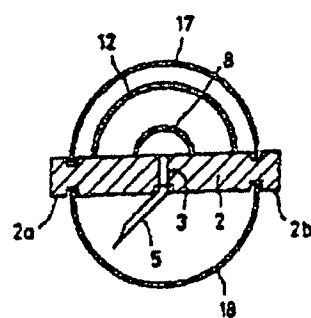
第 5 圖



第 3 圖



第 8 圖



第 7 圖

